

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	INTENSIVE REHABILITATION PROGRAM FOR SUBACUTE STROKE PATIENTS IN AN INPATIENT REHABILITATION FACILITY: DESCRIBING A PROTOCOL OF A PROSPECTIVE COHORT STUDY.
AUTHORS	Sartor, Monique; Grau-Sánchez, Jennifer; Guillén-Solà, Anna; Boza, Roser; Puig, Josep; Stinear, Cathy; Morgado-Perez, Andrea; Duarte, Esther

VERSION 1 – REVIEW

REVIEWER	Kamo, Tomohiko Nihon Hoken Iryo Daigaku, Department of Physical Therapy
REVIEW RETURNED	07-Dec-2020

GENERAL COMMENTS	<p>The authors will describe an intensive rehabilitation program for stroke patients in an inpatient rehabilitation facility, measuring the amount and type of therapies (physical, occupational and speech therapy) and reporting functional outcomes. The manuscript is interesting. However, there are some major concerns about the overall clarity of the manuscript. Below are a few comments and recommendations for changes.</p> <p>Introduction P8, line 1-26: The relationship between the amount of rehabilitation and outcomes in stroke patients has been reported in many different papers. You should state in more detail the differences with previous studies.</p> <p>P9, line 6: Please add your research hypothesis in Introduction.</p> <p>Methods P10, line 2: The type (PT, OT, ST) and amount of rehabilitation vary greatly depending on the severity of the stroke, presence of aphasia, agnosia, apraxia and dysphagia. These will significantly affect the outcome of your study. Suppose you find that a higher rate of physical therapy time improved outcomes. In that case, you cannot exclude the possibility that this is because the patients with a higher rate of physical therapy time don't have dysphagia or aphasia. Therefore, I find it difficult to prove the purpose of your study with the current study design. If you want to clarify the purpose of the present study, you need to intervene in the rate of rehabilitation in RCT.</p>
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	<p>P15, line 5: Please add main outcomes.</p> <p>P17, line 19: Please describe your response to the missing value. If you are going to compensate for the missing value, please also explain how you will do so.</p> <p>P17, line 19: Please, describe your statistical analysis methods in detail. If you are going to do a multivariate analysis, please describe the variables you will select. Also, please describe the rationale for your choice of that variable.</p>
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REVIEWER	<p>Tyson, Sarah</p> <p>University of Manchester, Stroke & Vascular Research Centre, School of Nursing, Midwifery & Social Work</p>
REVIEW RETURNED	17-Dec-2020

GENERAL COMMENTS	<p>This is a protocol for a prospective cohort study to measure the amount of therapy provided in an inpatient stroke rehabilitation unit. Follow up continues for up to 12 months after stroke – which is a plus. Throughout the study the authors refer to the recording/description of rehabilitation but it should be noted that the study only involves measuring the amount of time spent on different aspects of therapy. Thus, throughout the paper revisions are needed to specify that it is the amount of therapy provided by therapists during specific treatment sessions that is being recorded and described. Much of rehabilitation – input by other members of the MDT; non-direct input from therapists etc, etc – is not captured.</p> <p>The authors had worked with the therapists in their rehab unit to devise a list of the therapy activities to be measured but this has not been presented - it should be. What was done to validate the list? Was it piloted? How feasible is it to measure the time spent in different activities while also delivering them? In my experience it is very difficult, have the authors actually tried this out? How does the list compare to the other published ways of recording the content and amount of stroke therapy?</p> <p>The authors criticise previously studies attempting to record therapy provision saying that they 'only' involve recording the time spent, but the authors are proposing to 'only' measure the time spent. There are two points to make here – firstly several studies have developed detailed ways to record the content of therapy sessions and therapists activities – see the work of de Wit; Clarke; Tyson; Bernhardt. How does the proposed list of therapy activities compare to these? Why wasn't this previous work used as a basis for the proposed list? Secondly – how will work here to record the time spent on different therapy activities add to the previous studies which have recorded the time spent in therapy?</p> <p>In the introduction, the description of stroke rehabilitation is very focused on service delivery in Spain and some details are not universal. For example in other countries stroke services are not led by a rehab physician. It could be a stroke physician, geriatrician, neurologist or even no doctor at all. Three hours /day of therapy is not universal in some countries it is less, in some more. This could be reworded to make clear that the description is specific to Spain or to make it more general.</p>
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	<p>In some places, references to the literature is rather limited. For example – as noted above there are several studies of the content of stroke therapy and how to record it which have not been acknowledged. I disagree that the relationship between the amount of therapy and outcome is weak – again the referencing is selective and should include work by De Wit; Kwakkel, English; Langhorne; Tyson. I do agree that the simple mantra that 'more therapy is better' may be overly simplistic and the reality is more nuanced and complex. This point merits further consideration in the discussion section.</p> <p>I look forward to seeing the results of the study when it is completed</p>
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VERSION 1 – AUTHOR RESPONSE

REVIEWER 1 COMMENT:

AUTHORS' RESPONSE: We would like to thank the reviewer for this observation. It is true that several studies have explored the relationship between the amount of rehabilitation and the outcomes in stroke patients. We have reframed the introduction in order to include the most relevant evidence regarding this topic.

Introduction, page 5-6: Page 5, lines 24-25; Page 6, lines 1-13.

In the following weeks after the stroke, there is a time-limited period of increased plasticity that favors the establishment of new connections and forms of experience-dependent plasticity [13]. One of the biggest challenges in rehabilitation is to understand how to modulate the mechanisms of increased plasticity through the different elements of the rehabilitation process. In this vein, the intensity and the type of therapeutical activities are central elements that influence the degree of functional recovery [14]. The relationship between the amount of therapy and recovery has been extensively documented in animal models and in some clinical studies [15-18]. Intensive rehabilitation facilities usually provide rehabilitation programs that comprise 3 hours of therapy per day following international standards [19]. Training intensity is a relevant component of learning, but 3 hours of therapy do not guarantee 3 hours of training. Time is lost in transportation within the facility, preparation of activities and tasks and other activities that are not directly related to practice [15; 20]. Different studies measuring the amount of practice in stroke rehabilitation describe that the training dose provided differs substantially from what it is prescribed [21]. There is a need to investigate current practice models in inpatient rehabilitation facilities and describe how intensive rehabilitation programs are implemented [22-23].

A list of references were included:

14- Kwakkel G, Kollen B, Lindeman E. Understanding the pattern of functional recovery after stroke: facts and theories. *Restorative Neurology and Neuroscience*.2004; 22(3–5), 281–299. <https://doi.org/10.1177/1545968308317972>.

15- Krakauer JW, Carmichael T, Corbett D, Wittenberg GF. Getting Neurorehabilitation Right: What Can Be Learned From Animal Models? *Neurorehabil Neural Repair* 2012 26: 92. DOI: 10.1177/1545968312440745

16 - Chan L, Sandel ME, Jette AM, Appelman J, Brandt DE, Cheng P, Teselle M, Delmonico R, Terdiman JF, Rasch EK. Does postacute care site matter? A longitudinal study assessing functional recovery after a stroke. *Arch Phys Med Rehabil*. 2013;94:622–629 [PubMed](#) . doi: 10.1016/j.apmr.2012.09.033. 60.

17 - Wang H, Camicia M, Terdiman J, Mannava MK, Sidney S, Sandel ME. Daily treatment time and functional gains of stroke patients during inpatient rehabilitation. *PMR*. 2013;5:122–128 [PubMed](#) . doi: 10.1016/j.pmrj.2012.08.013.

- 18– Kwakkel G, Kollen, B, Lindeman, E. *Understanding the pattern of functional recovery after stroke: facts and theories. Restorative Neurology and Neuroscience.* 2004; 22(3–5), 281–299. <https://doi.org/10.1177/1545968308317972>
- 19- Winstein CJ, Stein J, Arena R , Bates B, Cherney LR, Cramer SC, et al. *Guidelines for Adult Stroke Rehabilitation and Recovery: A Guideline for Healthcare Professionals from the American Heart Association/American Stroke Association.* *Stroke*, 2016; 47(6), [PubMed](#) e98–e169. <https://doi.org/10.1161/STR.0000000000000098>
- 20- Zeiler SR, Krakauer JW. *The interaction between training and plasticity in the poststroke brain. Current Opinion in Neurology.* 2013; 26(6), 609–616. <https://doi.org/10.1097/WCO.0000000000000025>
- 21- Connell LA, McMahon NE, Simpson LA, Watkins, CL, Eng JJ. *Investigating measures of intensity during a structured upper limb exercise program in stroke rehabilitation: an exploratory study. Archives of Physical Medicine and Rehabilitation.* 2014; 95(12), 2410–2419. <https://doi.org/10.1016/j.apmr.2014.05.025>
- 22- Bernhardt J, Borschmann K, Boyd L, Carmichael ST, Corbett D, Cramer SC, et al. *Moving Rehabilitation Research Forward: Developing Consensus Statements for Rehabilitation and Recovery Research. Neurorehabilitation and Neural Repair.* 2017; 31(8), 694–698. <https://doi.org/10.1177/1545968317724290>
- 23- Bernhardt J , Hayward KS, Kwakkel G, Ward NS, Wolf, SL., Borschmann K et al. *Agreed Definitions and a Shared Vision for New Standards in Stroke Recovery Research: The Stroke Recovery and Rehabilitation Roundtable Taskforce. Neurorehabilitation.*

REVIEWER 1 COMMENT: P9, line 6: Please add your research hypothesis in Introduction.

AUTHORS' RESPONSE: Thank you very much for your suggestion. Although the nature of this study is descriptive, we have included three hypothesis related to the implementation of the therapy program and the functional recovery of stroke patients.

Introduction, page 7, lines 15-22:

“The study aims to describe an intensive rehabilitation program for stroke patients in an inpatient rehabilitation facility, measuring the amount and type of therapies (physical, occupational and speech therapy) and reporting functional outcomes. Based on previous research, we hypothesize that the amount of therapy delivered is less than what it is planned, and that most therapy activities will be directed to reduce deficits in body functions. In this vein, we also expect that patients show major improvements on body functions during their stay at the inpatient rehabilitation facility, and that recovery of autonomy in activities of daily living will be more prominent at 3- and 6-months post-discharge. ”

REVIEWER 1 COMMENT : P10, line 2: The type (PT, OT, ST) and amount of rehabilitation vary greatly depending on the severity of the stroke, presence of aphasia, agnosia, apraxia and dysphagia. These will significantly affect the outcome of your study. Suppose you find that a higher rate of physical therapy time improved outcomes. In that case, you cannot exclude the possibility that this is because the patients with a higher rate of physical therapy time don't have dysphagia or aphasia. Therefore, I find it difficult to prove the purpose of your study with the current study design. If you want to clarify the purpose of the present study, you need to intervene in the rate of rehabilitation in RCT.

AUTHORS' RESPONSE: Thank you very much for this observation. The main aim of this study is to describe the rehabilitation program, recording the type of activities and the amount of time spent on each of them. We will also evaluate patients' functionality to describe the time-course of their recovery. This study does not intend to establish a relationship between the amount of therapy delivered and the patients' recovery degree. To do that, other types of design including a control group would be more suitable. Our unit is organized in a way that patients receive one hour of each therapy (speech, physical and occupational therapy) and they do not increase the amount of therapy if they do not need other interventions (for instance, physical therapy is not increased in patients who do not need speech therapy). However, we agree with the reviewer that the therapy activities delivered, and the time spent in each of them will depend on the individual deficits of each patient. This limitation is inherent to the personalization

of the intervention program and it could be a potential confounder when generalizing the results. We have addressed this issue in the discussion section as a limitation.

Discussion section, page 17, lines 13-15:

“The therapy activities and time spent in each of them will depend on the individual deficits of each patient. This represents an inherent limitation for the generalization of results in rehabilitation studies since interventions are tailored to the patient.”

REVIEWER 1 COMMENT P15, line 5: Please add main outcomes.

AUTHORS' RESPONSE: Thank you for this suggestion. We have renamed the different sections regarding the evaluation of patients. The previous section 'Assessment' is now 'Evaluation of patients' and includes subsections 'Baseline variables' and 'Outcomes'. We have maintained the division of outcomes considering the International Classification of Functioning. Therefore, the reviewer can find 'Body structure and function outcomes', 'Activity outcomes' and 'Participation outcomes'. Considering the descriptive nature of the study, we do not have a primary outcome since the intensive rehabilitation program is a complex intervention targeting multiple deficits and problems. We think that the three domains of functioning (body structure and function, activity level and participation) provide a comprehensive view of the patients' recovery without focusing in a solely outcome.

The description of all this outcomes are provided on the Methods section - page 14 to 15.

REVIEWER 1 COMMENT P17, line 19: Please describe your response to the missing value. If you are going to compensate for the missing value, please also explain how you will do so.

AUTHORS' RESPONSE: Thanks for your comment: authors have decided to use the imputation method to deal with missing data, using the last observation carried forward analysis. This information was added into the main manuscript on Data analysis; page 16, lines 13-14.

“The last observation carried forward will be used to deal with missing value”

REVIEWER 1 COMMENT P17, line 19: Please, describe your statistical analysis methods in detail. If you are going to do a multivariate analysis, please describe the variables you will select. Also, please describe the rationale for your choice of that variable.

AUTHORS' RESPONSE: Thank you very much for this observation. We have modified the information provided on Statistical analysis, clarifying some aspects of the analysis. In addition, we would like to highlight that this is an observational study without a control group. For that, the main point of this study is to describe the amount of therapy received by the patients who are admitted at our Neurorehabilitation unit, and to describe the changes observed on the study outcomes across study period. We do not intent to establish a causal relationship. In this vein, with the results of this study, we intend to answer the research question at level 1, which is the description of the rehabilitation program delivered in our unit. A deep understanding about program's intensity will allow us in the future to answer the research question at level 2, which would be to establish possible relationships between variables, and at level 3 which would require a control, to test a hypothesis related with the intensity of the intervention and the changes on the outcomes.

Methods Section, Data Analysis: page 16, lines 12-13:

"All patient's clinical, demographic, and assessment data will be kept in a secure database. Data on recruitment and the transcription of the therapy dose register will also be included. Analyses will be carried out using IBM SPSS Statistics 24. The continuous variables will be described with the mean and standard deviation or with the median and inter-quartile range, depending on their distribution. The categorical variables will be described as percentages. To describe the stroke rehabilitation programme, the amount of time spent on each type of activity during the therapy sessions will be reported as mean and standard deviation. In order to minimize missing data, all questionnaires are user friendly and collected electronically, and all personnel related to the study are trained to identify and engage participants who may be at risk of dropout during follow up. ANOVA for repeated measures will be used to describe the changes in clinical assessment measures across the four-time points. The last observation carried forward will be used to deal with missing value."

REVIEWER 2 COMMENT: This is a protocol for a prospective cohort study to measure the amount of therapy provided in an inpatient stroke rehabilitation unit. Follow up continues for up to 12 months after stroke –which is a plus. Throughout the study the authors refer to the recording/description of rehabilitation but it should be noted that the study only involves measuring the amount of time spent on different aspects of therapy. Thus, throughout the paper revisions are needed to specify that it is the amount of therapy provided by therapists during specific treatment sessions that is being recorded and described. Much of rehabilitation – input by other members of the MDT; non-direct input from therapists etc, etc – is not captured.

AUTHORS' RESPONSE: Thank you very much for your comment. It is true that our study will only describe therapy activities delivered and the time spent in each of them, and that the rehabilitation program is more complex than that. Aspects such as the therapeutic relationships established with the patient, the direct and non-direct inputs during therapy sessions, how other staff members (physicians, nurses, nurse assistants, porters) interact with the patient in a supporting manner, and environmental factors of our unit favoring recovery will not be measured. We acknowledge that these aspects play a crucial role in the rehabilitation process and we have addressed this issue in the discussion section. Moreover, we have revised the manuscript to specify that we are describing activities and time spent and changed those expressions that could lead to confusion.

Discussion, page 17, lines 20-26.

"This study only allows us to quantify the time allocated to each activity during specific treatment sessions, but does not register qualitative or patient-centered aspects. For instance, we will not measure the motivation of the patient, which is an aspect that may influence the effectiveness of the therapies. Moreover, there are other elements of the rehabilitation process that play a crucial role that will not be measured such as the therapeutic relationships established with the patient, the direct and non-direct inputs during therapy sessions, how other staff members (physicians, nurses, nurse assistants, porters) interact with the patient in a supporting manner, and environmental factors of our unit favoring recovery."

REVIEWER 2 COMMENT: The authors had worked with the therapists in their rehab unit to devise a list of the therapy activities to be measured but this has not been presented - it should be. What was done to validate the list? Was it piloted? How feasible is it to measure the time spent in different activities while also delivering them? In my experience it is very difficult, have the authors actually tried this out? How does the list compare to the other published ways of recording the content and amount of stroke therapy?

AUTHORS' RESPONSE: Thank you very much for your comments and suggestions. We will present as supplementary document the registry tool devised. Indeed, we also attached this document at the end of this document. The register of activities delivered in each scheduled therapy (physiotherapy, speech therapy and occupational therapy) was developed using as references the following articles: Bode et al., 2004 and Veerbeek et al., 2014. Following a Delphi method, an advisory group formed by one medical doctor, two physiotherapists, one occupational therapist and one speech therapist proposed a first set of therapy interventions. Finally, the list was revised to reach enough consensus between the group. As the therapists designed this material, they also consider the feasibility to complete the registry tool while treating the patients. The list includes 36 therapy activities (PT, TO or SLT) and is compared with other classification methods. We do not consider the need to carry out a pilot study because this registry tool only reflects the activities and interventions delivered in our rehabilitation program.

REVIEWER 2 COMMENT: The authors criticize previously studies attempting to record therapy provision saying that they 'only' involve recording the time spent, but the authors are proposing to 'only' measure the time spent. There are two points to make here – firstly several studies have developed detailed ways to record the content of therapy sessions and therapists activities – see the work of de Wit; Clarke; Tyson; Bernhardt. How does the proposed list of therapy activities compare to these? Why wasn't this previous work used as a basis for the proposed list? Secondly – how will work here to record the time spent on different therapy activities add to the previous studies which have recorded the time spent in therapy?

AUTHORS' RESPONSE: Thank you very much for your comment. This registry tool will permit to record the time spent on each activity during specific treatment sessions, this will allow us to have a deep understanding about the content of each scheduled therapy (physiotherapy, speech therapy and occupational therapy). In this vein, this registry tool not only measures the time spent on each activity but also describes the interventions delivered on each specific session. The register tool was developed in two different moments: firstly, the work from Bode et al., 2004 and Veerbeek et al., 2014 was used as a guide to devise the list of activities performed on specific treatment sessions. Secondly, following a Delphi method, the list was finally adapted to the reality of our program.

Methods and Analysis page 12, lines 12-21:

"The register of activities delivered in each scheduled therapy (physiotherapy, speech and occupational therapy) was developed on the basis of the proposals of Bode et al 2004 [28] and Veerbeek et al 2014 [31]. In accordance to Delphi method, an advisory group formed by one medical doctor, two physiotherapists, one occupational therapist and one speech therapist proposed a first set of therapy interventions. Only interventions and activities available in our rehabilitation program were included, together with those that the group considered that should be added since they are part of our daily practice. Finally, the list was revised to reach enough consensus between the group. This register allows a daily recording of the number of minutes performed in each activity stratified by discipline during specific treatment sessions and thus know what interventions are carried out and how much time is dedicated to each of them."

REVIEWER 2 COMMENT: In the introduction, the description of stroke rehabilitation is very focused on service delivery in Spain and some details are not universal. For example in other countries stroke services are not led by a rehab physician. It could be a stroke physician, geriatrician, neurologist or even no doctor at all. Three hours /day of therapy is not universal in some countries it is less, in some more. This could be reworded to make clear that the description is specific to Spain or to make it more general.

AUTHORS' RESPONSE: Thanks for your comment, this information was reframed in the Introduction in order to make a more general description about how the rehabilitation programs are delivered in most European countries.

Introduction page 5, lines 8-13:

“Rehabilitation is a patient-centered process delivered by a multidisciplinary team, including medical doctors, physical, occupational and speech therapists, nurses, social workers, and neuropsychologists, which is led by physicians trained in Physical Medicine and Rehabilitation After discharge from the stroke unit, the post-acute inpatient care services for stroke patients include rehabilitation facilities and long-term care hospitals [6]. Inpatient rehabilitation facilities provide hospital-level care and should offer intensive programs of therapy.”

REVIEWER 2 COMMENT: In some places, references to the literature is rather limited. For example – as noted above there are several studies of the content of stroke therapy and how to record it which have not been acknowledged. I disagree that the relationship between the amount of therapy and outcome is weak – again the referencing is selective and should include work by De Wit; Kwakkel, English; Langhorne; Tyson. I do agree that the simple mantra that ‘more therapy is better’ may be overly simplistic and the reality is more nuanced and complex. This point merits further consideration in the discussion section.

AUTHORS' RESPONSE: Thank you very much for your observation. We have included more information regarding the relationship between training intensity and recovery in the Introduction and Discussion sections.

Introduction, page 5, lines 24-25; page 6, lines 1-13.

“In the following weeks after the stroke, there is a time-limited period of increased plasticity that favors the establishment of new connections and forms of experience-dependent plasticity [13]. One of the biggest challenges in rehabilitation is to understand how to modulate the mechanisms of increased plasticity through the different elements of the rehabilitation process. In this vein, the intensity and the type of therapeutical activities are central elements that influence the degree of functional recovery [14]. The relationship between the amount of therapy and recovery has been extensively documented in animal models and in some clinical studies [15-18]. Intensive rehabilitation facilities usually provide rehabilitation programs that comprise 3 hours of therapy per day following international standards [19]. Training intensity is a relevant component of learning, but 3 hours of therapy do not guarantee 3 hours of training. Time is lost in transportation within the facility, preparation of activities and tasks and other activities that are not directly related to practice [15; 20]. Different studies measuring the amount of practice in stroke rehabilitation describe that the training dose provided differs substantially from what it is prescribed [21]. There is a need to investigate current practice models in inpatient rehabilitation facilities and describe how intensive rehabilitation programs are implemented [22-23]”.

Discussion, page 17, lines 1-5:

“The amount of rehabilitation therapy contributes to functional recovery after stroke [12], but different studies have pointed out a discrepancy between the planned therapy hours and the actual practice time

[19-23]. The optimal dose-response in stroke rehabilitation has not been established and further research is needed to elucidate and better understand the relationship between training intensity and recovery”

VERSION 2 – REVIEW

REVIEWER	Tyson, Sarah University of Manchester, Stroke & Vascular Research Centre, School of Nursing, Midwifery & Social Work
REVIEW RETURNED	06-Apr-2021

GENERAL COMMENTS	<p>The authors have made clear efforts to address the issues raised in the 1st review. Thank you. The manuscript is much improved. However, I think it is over-generous to describe this as a detailed description of the intensive rehabilitation. It is merely an estimate of the time spent in different types of direct patient contact during therapy sessions in a single in-patient rehabilitation centre.</p> <p>I still have concerns about the recording tool. It is rather generous to call its development a Delphi technique- it appears much more that some of the people delivering the rehab in the centre got together and listed what they did. Has the form been piloted?? Do the authors know that it's feasible to complete and comprehensive of all the treatment options? The number and range of activities seems very limited and the descriptions are vague. Is this really all the therapists do? I would find it very difficult to complete the recording tool as there is replication between items - How does “STS training + inclined plane” differ from “Training the transfer from sit-to-stand”? How does “balance training during activities” differ from “sitting and standing balance training without biofeedback”? Is biofeedback ever used?</p> <p>Other items include multiple elements – for example ‘active exercise and active assisted mobilisations’ which are two different things. Do therapists need to have used both of these? Do they record the time spent in each or both together?</p> <p>How will the time be recorded? Are stop watches used (which is very difficult to do in real life) or are the therapists asked to estimate the time they have spent on different activities (which is notoriously inaccurate).</p> <p>In the limitations the authors need to acknowledge that they are only recruiting a sub-set of people with stroke who are deemed to need rehabilitation, and only recording the estimated duration of direct patient therapy contact – this is not comprehensive as far as stroke patients or therapy is concerned. Has the recording tool been validated in other centres. Can the authors be confident that it represents therapy activity in Spain or Barcelona or is it just the participating centre?</p> <p>It would also be helpful to acknowledge that, although convenient, data collection at clinical time points (admission and discharge) rather than time since stroke limits the usability of the data as these points vary between individuals.</p>
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VERSION 2 – AUTHOR RESPONSE

REVIEWER 2 COMMENT: The authors have made clear efforts to address the issues raised in the 1st review. Thank you. The manuscript is much improved.

AUTHORS' RESPONSE: Thank you very much for your comment.

REVIEWER 2 COMMENT: However, I think it is over-generous to describe this as a detailed description of the intensive rehabilitation. It is merely an estimate of the time spent in different types of direct patient contact during therapy sessions in a single in-patient rehabilitation center. I still have concerns about the recording tool. It is rather generous to call its development a Delphi technique- it appears much more that some of the people delivering the rehab in the center got together and listed what they did. Has the form been piloted?? Do the authors know that it's feasible to complete and comprehensive of all the treatment options? The number and range of activities seems very limited and the descriptions are vague. Is this really all the therapists do?

AUTHORS' RESPONSE: We would like to thank the reviewer for this observation. We agree with the reviewer that our study will only measure the time spent in different activities during therapy sessions. For that reason, we have removed the following sentence: "*This study will provide a comprehensive description of an intensive rehabilitation program for subacute stroke patients delivered at an inpatient rehabilitation unit*". We have changed this sentence for the following: "*This study will provide a description of an intensive rehabilitation program for subacute stroke patients delivered at our inpatient rehabilitation unit*" (Discussion page 16 lines 17-18). Since this study will be conducted in a single rehabilitation center, along the manuscript, we have changed "*at an inpatient rehabilitation unit*" for "*at our inpatient rehabilitation unit*" in order to highlight that the program description reflects the activities performed just and solely at our center.

Regarding the recording tool, we did not use a comprehensive Delphi method to agree on the content of the registry tool. We would like apologize for this misunderstanding and we already removed this information from the main manuscript. The development of the registry tool was carried out by an advisory group formed by one medical doctor, two physiotherapists, one occupational therapist and one speech therapist. They proposed a first set of therapy interventions and this list was revised to reach consensus between the group. As the therapists designed this material, they also considered the feasibility to complete the registry tool while treating the patients. Indeed, nowadays we are carrying out an analysis from the first patients included on the study in order to check how comprehensive and feasible the registry tool may be. For that, we have decided to add the following statement on the discussion section: *Future research would be needed in order to check how comprehensive this registry tool is and assess its feasibility.*

Discussion section, page 18, line 8-10.

REVIEWER 2 COMMENT: I would find it very difficult to complete the recording tool as there is replication between items - How does “STS training + inclined plane” differ from “Training the transfer from sit-to-stand”? How does “balance training during activities” differ from “sitting and standing balance training without biofeedback”? Is biofeedback ever used? Other items include multiple elements – for example ‘active exercise and active assisted mobilisations’ which are two different things. Do therapists need to have used both of these? Do they record the time spent in each or both together?

AUTHORS’ RESPONSE: Thank you very much for your observation. We have reframed some items of the registry tool in order to make them clearer. You can find a clarification below for each of the items of which the reviewer had a concern on. As mentioned, some of the items were reframed on the registry tool, and these changes are marked in blue.

How does “STS training + inclined plane” differ from “Training the transfer from sit-to-stand”: We would like to apologize for that, this was a wording problem. The term that we would like to use for “STS training + inclined plane” would be: standing training using standing stretchers. This activity is proposed for patients that require this device to train standing. This was reframed on the registry tool.

Another clarification that we would like to make is about the item “Training the transfer from sit-to-stand”. This was a misspelling. On this item authors intend to cover all transfer training, for that we have reframed this item and changed to “Transfer training”.

How does “balance training during activities” differ from “sitting and standing balance training without biofeedback”? Is biofeedback ever used? Balance training during activities covers a more dynamic balance training in which the patient is challenged to achieve, restore or maintain the balance while performing different activities, or a dual-task activity in which one of them is the balance training. The sitting balance focuses on training trunk control. In order to make this item clearer authors have changed “sitting training” for “trunk control training”. Biofeedback is not used, this item was present in the first version of the registry tool, and after the second agreement it was removed from the original version, this was a misunderstanding, sorry for that.

Active exercise and active assisted mobilizations’ which are two different things. Do therapists need to have used both of these? Thank you for the suggestion. We agree with the reviewer and have modified this item to just include “active exercises”, removing the ‘mobilizations’.

REVIEWER 2 COMMENT: How will the time be recorded? Are stop watches used (which is very difficult to do in real life) or are the therapists asked to estimate the time they have spent on different activities (which is notoriously inaccurate).

AUTHORS’ RESPONSE: Thanks for your comment, each therapist will record the time spent in each activity during the therapy session. We acknowledge that the method used in our protocol to register the

activities will be an estimation of the time devoted to each activity. Authors recognize the limitations and inaccuracy of this method, indeed these limitations were addressed on Discussion section. However, the use of stopwatches could also be inaccurate and very difficult to carry out in real life. We do believe that using more objective tools to measure the activities such as video or auditing records of third parties may not guarantee that the information would be more reliable. In order to limit the inaccuracy of the method used in our protocol, all participating therapists have agreed to provide reliable data when reporting therapy sessions.

“The data collected in this study will rely on the information provided by the therapists, and although all participating therapists have agreed to provide reliable data when reporting therapy sessions, there might be a social desirability bias and inaccuracy”. - Discussion section, page 17, line 13-15.

REVIEWER 2 COMMENT: In the limitations the authors need to acknowledge that they are only recruiting a sub-set of people with stroke who are deemed to need rehabilitation, and only recording the estimated duration of direct patient therapy contact – this is not comprehensive as far as stroke patients or therapy is concerned. Has the recording tool been validated in other centers. Can the authors be confident that it represents therapy activity in Spain or Barcelona or is it just the participating center?

AUTHORS’ RESPONSE: Thanks for your suggestion, authors have acknowledged this on the discussion section: *“Indeed, we acknowledge that the registry tool is just an estimation of the time spent on specific activities during therapies, which is not comprehensive as far as therapies are concerned.”*

Discussion section page 17, line 15-17

The rehabilitation program carried out at our unit is addressed to stroke patients who have a good functional prognosis according to the following criteria: i) no major cognitive deficits affecting comprehension (MoCA ≥ 20), ii) low comorbidity (Charlson Index < 3) and iii) functional independence before the stroke (mRS ≤ 2). This can limit the generalization of results to the stroke population and other clinical settings with different profiles of stroke patients. The description provided in this protocol reflects our clinical practice and our intention with this study is to describe the content of the inpatient rehabilitation program carried out at our center. In our context, there are only three centers in Catalonia region offering intensive rehabilitation programs for stroke patients (3 hours per day of ST, OT and PT). These programs are implemented and ruled by the National Health System (Stroke Strategic Plan, Catalan Health Department). Therefore, our study represents a first effort to describe the rehabilitation program in an inpatient unit in our context. In the

future, we think it would be interesting to share this registry tool with these other centers in order to check the validity of this tool and compare rehabilitation programs and patients' recovery across centers.

REVIEWER 2 COMMENT: It would also be helpful to acknowledge that, although convenient, data collection at clinical time points (admission and discharge) rather than time since stroke limits the usability of the data as these points vary between individuals.

AUTHORS' RESPONSE: Thank you very much for your observation. We decided to consider as a baseline the moment that the patient is admitted to the rehabilitation unit for practical and methodological reasons. From a practical point of view, we thought it was best to evaluate patients when they arrived. From a methodological point of view, all patients are admitted to our unit within the first 2 weeks after the stroke and spent 3 weeks at it, therefore there might be a bit of variability in days since the stroke. Moreover, our focus is to describe the rehabilitation program rather than to investigate in depth the overall evolution of patients in a temporal scale of days. Therefore, we decided to evaluate patients at the beginning and at the end of the program. We do consider time since stroke as a descriptive variable, and we collect this information for all patients since it can be a confounding variable and we acknowledge the limitations this may represent.

VERSION 3 – REVIEW

REVIEWER	Tyson, Sarah University of Manchester, Stroke & Vascular Research Centre, School of Nursing, Midwifery & Social Work
REVIEW RETURNED	14-Jul-2021
GENERAL COMMENTS	the authors have thoroughly addressed the issues raised in the review